

STATE PROCUREMENT OFFICE  
NOTICE OF REQUEST FOR EXEMPTION  
FROM HRS CHAPTER 103D

13 MAY 10 P12:12

STATE PROCUREMENT OFFICE  
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health, CDPHND, Tuberculosis Control Branch  
Name of Requesting Department

Pursuant to HRS § 103D-102(b)(4) and HAR chapter 3-120, the Department requests a procurement exemption for the following:

1. Describe the goods, services or construction: Tuberculosis Drugs. (Tubersol or Apisol solution 10/dose vial and/or 50/dose vial). The State Hawaii Administrative Rules, Title 11, Department of Health, Chapter 164.1, Emergency Rules Relating to Examinations for Tuberculosis (effective 4/11/13) has temporarily suspended the TB clearance requirements due to the nationwide shortage of testing solution. Manufacturers of the PPD solution have been experiencing delays in production since November 2012. It is expected adequate supplies will be available several months from now. Therefore, testing for school personnel, students, food handlers and workers in health care, domiciliary care, daycare and residential care facilities have been suspended.	
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2. Vendor/Contractor/Service Provider: R. Weinstein		3. Amount of Request: \$ 100,000
4. Term of Contract: From: Upon SPO approval To: 6 mons after SPO Appl	5. Prior SPO-007, Procurement Exemption 12-075-D (PE):	

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means: SEE ATTACHMENT
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7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider: Normally, the Tuberculosis Control Branch has a SPO-007 to use HRSA 340B vendors and would go to SPO PVL 12-09, MMCAP vendor. However, due to shortage the TB program has been calling various vendors based on referrals to solicit availability of Tubersol and Apisol, other companies contacted are Moore Medical (had supplies but were not HCE compliant and not interested in complying with Hawaii HCE law), Sanofi Pasteur, and VersaPharm. R. Weinstein is registered with HCE and is compliant and able to supply program with limited amounts of the Tubersol solution. We will need a reserve of 10,000 doses of Tubersol or Apisol before we can re-start the TB skin tests for those whom are currently suspended. There maybe additional request as we find other vendors with Tubersol/Apisol and are willing and able to become HCE compliant to purchase needed supplies.
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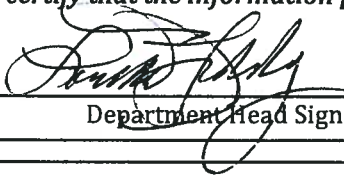
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8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).

\*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	e-mail address
Lynn Donovan*	CDPHND, TB Branch	832-5731	lynn.donovan@doh.hawaii.gov
Trudy Murakami, PHAO IV	CDPHND, TB Branch	832-5737	trudy.murakami@doh.hawaii.gov

*All requirements/approvals and internal controls for this expenditure is the responsibility of the department.  
I certify that the information provided above is, to the best of my knowledge, true and correct.*



Department Head Signature

Date

5/9/13

**For Chief Procurement Officer Use Only**

Date Notice Posted: 5.13.13

Inquiries about this request shall be directed to the contact named in No. 8. Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

[state.procurement.office@hawaii.gov](mailto:state.procurement.office@hawaii.gov)

Chief Procurement Officer (CPO) Comments:

This request is disapproved as department failed to comply with the CPO requirements provided in PE-12-075D and PE-13-034B for posting the award on the Awards Reporting System. Failing to comply with CPO requirements, procurement circulars and directives, the Hawaii Public Procurement Code and its administrative rules are procurement violations. Department shall submit form SPO-016, *Report of Procurement Violation: Findings and Corrective Actions and/or Request for After-the-Face Payment Approval*, to explain why the department failed to post the award as required.

If there are any questions, please contact Donn Tsuruda-Kashiwabara at 586-0565 or [donna.tsuruda-kashiwabara@hawaii.gov](mailto:donna.tsuruda-kashiwabara@hawaii.gov).

☐ Approved

☒ Disapproved

☐ No Action Required



Chief Procurement Officer Signature

5/21/2013

Date

**RESPONSE TO ITEM #6:**

Currently, there is a national shortage of Tubersol & Aplisol (PPD) solution and the State's TB program has been significantly impacted by this situation. To avoid non-compliance with meeting terms under Hawaii Administrative Rules, Title 11, Department of Health, Chapter 164, to gain a TB Clearance Certificate, the TB program has instituted a temporary suspension of the TB skin test and limited to only the most "high risk" in the State's population and has evoked emergency rules for the next 120 days until adequate supplies are received to re-establish normal testing operations. This suspension of rules is a one-time measure with no extension. If the situation persists beyond the 120 days, the Governor will need to issue a Public Health Emergency proclamation.

The TB Control Branch participates in the 340B Drug Pricing Program which resulted from the enactment of Public Law 102-585, the Veterans Health Care Act of 1992. The 340B Drug Discount Program is managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). The Branch also uses SPO Price List Contract No. 12-09, MMCAP Contract No. MMS10000. AmeriSourceBergen Drug Corporation is the vendor for this contract. At present, HRSA vendors and AmeriSourceBergen do not have supplies of Tubersol or Aplisol available. AmeriSourceBergen expects supplies in at the end of May. We are seeking an exemption only until our preferred and compliant vendor is able to reinstate normal supplies to the State. We expect this will take two to three months.

Recently, the State's TB Program was able to find a vendor with supplies of PPD solution and is willing and able to ship supplies to us. However, the vendor is not on either authorized list that the TB program is able to purchase; thus, the request for exemption. The program plans to build the PPD supply in anticipation of resuming normal TB skin testing operations statewide after the 120 days has expired. This supply is also expected to last until the vendors are able to ship new supplies from authorized vendors (once they have supplies in hand and are able to ship to Honolulu).

At this time the TB program is submitting this exemption to purchase at a market rate from R. Weinstein (is not a participating vendor under the 340B or MMCAP programs). The TB program requires approximately 10,000 doses (a two-month supply) to resume normal TB skin testing operations and is planning to stockpile supplies purchased from R. Weinstein (we presently plan to purchase 200 vials (10 dose vials) each week). We hope to get 10,000 doses to start operations after the 120 days has expired. This should provide adequate PPD solutions until either our 340B or MMCAP vendors are able to ship additional supplies to Honolulu. At this time, the program has exhausted all contacts of vendors that may have supplies of Tubersol/Aplisol and has also enlisted assistance from the federal Center for Disease and Prevention Control to determine if any other vendor has supplies of Tubersol or Aplisol that is available to us.

PE 12-0940